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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,791	12/20/2001	James W. Clark	KCX-391(16284)	9606
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DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			BOYD, JENNIFER A	
			ART UNIT	PAPER NUMBER
			1771	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

CP

Office Action Summary	Application No. 10/027,791	Applicant(s) CLARK ET AL.	
	Examiner Jennifer A Boyd	Art Unit 1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 April 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 and 49 - 54 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-38 and 49 - 54 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Applicant's Amendments and Accompanying Remarks, filed April 26, 2004, have been entered and have been carefully considered. Claims 1, 25, 27, 34, 35 and 38 are amended, claims 49 – 54 are added and claims 1 – 38 and 49 – 54 are pending. Despite these advances, the invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1 – 9, 11 – 38 and 49 - 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (US 2002/0103098 A1).

Harrison et al. is directed to a low residue aqueous hard surface cleaning and disinfecting composition (Title).

As to claim 1, Harrison teaches an aqueous-based cleaning composition comprising a quaternary ammonium surfactant compound having germicidal properties (Abstract). Harrison teaches that the quaternary ammonium compound is present in an amount of from about 0.0025% to about 0.5% wt based on the total weight of the inventive composition (page 2, [0017]). Harrison teaches that the composition may be applied to a hard surface by using a wet wipe comprising a non-woven fabric (page 7, [0091]). The Examiner equates the non-woven fabric to Applicant's "substrate".

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As to claim 2, Harrison teaches that benzalkonium chloride may be used as the quaternary ammonium compound (page 2, [0016]). It should be noted that on page 14, line 2 of the Applicant's Specification, the Applicant indicates that benzalkonium chloride meets the requirements of the formula in claim 2.

As to claim 3, Harrison teaches that BARDAC 2080 may be used as the quaternary ammonium compound (page 2, [0016]). It should be noted that on page 14, line 23 of Applicant's Specification, the Applicant indicates that BARDAC 2080 meets the requirements of the formula in claim 3.

As to claims 4 and 5, Harrison teaches that the quaternary ammonium compound is present in an amount of from about 0.0025% to about 0.5% wt based on the total weight of the inventive composition (page 2, [0017]).

As to claim 6, Harrison teaches that a chelating agent may be present in the formulation (page 4, [0056]). It should be noted that it is known in the art that a chelating agent is a sequestrant. Harrison teaches that the chelating agent may be present in amounts less than 2.5% by weight of the composition (page 5, [0056]).

As to claim 7, Harrison teaches that the composition may contain a nonionic surfactant (page 4, [0056]).

As to claim 8, Harrison teaches that the nonionic surfactant is present in amounts less than 2.5% by weight of the composition (page 5, [0056]).

As to claim 9, Harrison teaches that the composition comprises an alkylene glycol solvent such as propylene glycol n-butyl (pages 3 and 4, [0046]). It should be noted that on page 23, lines 20 – 30 of the Applicant's Specification, the Applicant indicates that propylene glycol is a

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non-aqueous solvent. Harrison teaches that the propylene glycol n-butyl is present in amount ranging from 0.01% to 10% wt (page 4, [0046]).

As to claim 26, Harrison teaches that the composition can be applied to a hard surface by means of a wet wipe comprising a non-woven fabric (page 7, [0091]).

As to claims 27 – 28 and 35, Harrison teaches an aqueous-based cleaning composition comprising a quaternary ammonium surfactant compound having germicidal properties (Abstract). Harrison teaches that the quaternary ammonium compound is present in an amount of from about 0.0025% to about 0.5% wt based on the total weight of the inventive composition (page 2, [0017]). Harrison teaches that benzalkonium chloride may be used as the quaternary ammonium compound (page 2, [0016]). Harrison teaches that the composition may be applied to a hard surface by using a wet wipe comprising a non-woven fabric (page 7, [0091]).

As to claim 29, Harrison teaches that a chelating agent may be present in the formulation (page 4, [0056]). It should be noted that it is known in the art that a chelating agent is a sequestrant. Harrison teaches that the chelating agent may be present in amounts less than 2.5% by weight of the composition (page 5, [0056]).

As to claim 30, Harrison teaches that the composition may contain a nonionic surfactant (page 4, [0056]). Harrison teaches that the nonionic surfactant is present in amounts less than 2.5% by weight of the composition (page 5, [0056]).

As to claim 31, Harrison teaches that the composition comprises an alkylene glycol solvent such as propylene glycol n-butyl (pages 3 and 4, [0046]). It should be noted that on page 23, lines 20 – 30 of the Applicant's Specification, the Applicant indicates that propylene glycol

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is a non-aqueous solvent. Harrison teaches that the propylene glycol n-butyl is present in amount ranging from 0.01% to 10% wt (page 4, [0046]).

As to claim 36, Harrison teaches that composition may contain a nonionic surfactant (page 4, [0056]), chelating agent (page 4, [0056]) and/or non-aqueous solvent (pages 3 and 4, [0046]) may be present in the composition.

As to claims 52 – 54, Harrison teaches that the wipe an comprise wood pulp fibers (page 7, [0092]) which are known in the art to be cellulosic.

As to claims 1, 25, 27, 34, 35, 38 and 49 – 51, Harrison discloses the claimed invention except for that the quarternary ammonium compound is present in an amount less than 2000 parts per million of said solution as stated in claims 1, 27 and 35, the quarternary ammonium compound is present in the amount of about 150 to about 400 parts per million of solution as stated in claims 25, 34 and 38 and the quarternary compound is present in an amount of less than about 400 parts per million of the solution as stated in claims 49 - 51. It should be noted that the amount of quarternary ammonium compound is a result effective variable. For example, the amount of the quarternary ammonium compound present directly impacts the biocidal effectiveness (Harrison, column 9, lines 1 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the amount of the quarternary ammonium compound present in an amount less than 2000 parts per million of said solution as stated in claims 1, 27 and 35 the quarternary ammonium compound is present in the amount of about 150 to about 400 parts per million of solution as stated in claims 25, 34 and 38 and the quarternary compound is present in an amount of less than about 400 parts per million of

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the solution as stated in claims 49 – 51 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to create the wipe with the optimum amount of quarternary ammonium compound in order to have maximal biocidal effectiveness.

As to claims 1, 11 - 24, 27, 32 – 33, 35 and 37, although Harrison does not explicitly teach the claimed log reduction for E. Coli of at least about 2 as required by claim 1, the pH of the sanitizing formulation is greater than about 8 as required by claim 11, the pH of the sanitizing formulation is between about 9 and 12 as required by claim 12, the log reduction for E. Coli is of at least about 3 as required by claims 13 and 27, the log reduction for E. Coli is of at least about 4 as required by claim 14, the log reduction for E. Coli is of at least about 5 as required by claim 15, the log reduction for S. Aureus is of at least about 2 as required by claim 16, the log reduction for S. Aureus is of at least about 3 as required by claims 17 and 27, the log reduction for S. Aureus is of at least about 4 as required by claim 18, the log reduction for S. Aureus is of at least about 5 as required by claim 19, the kill efficiency ratio of a least about 10 as required by claim 20, the kill efficiency ratio of a least about 100 as required by claims 21 and 35, the kill efficiency ratio of a least about 400 as required by claim 22, the antimicrobial reduction of less than 95% as required by claim 23, the antimicrobial reduction between about 60 – 80% as required by claim 24, the log reduction for E. Coli is of at least about 4 as required by claim 32, the log reduction for S. Aureus is of at least about 4 as required by claim 33 and the kill efficiency ratio of a least about 200 as required by claim 37, it is reasonable to presume that the properties are inherent to Harrison. Support for said presumption is found in the use of like

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materials (i.e. a substrate comprising a composition containing water and a quaternary ammonium compound in an amount of 0.0025% to about 0.5% wt) which would result in the claimed properties. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties above would obviously have been present once the Harrison product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

As to claims 1, 27 and 35, Harrison discloses the claimed invention except for that the sanitizing formulation is present in the substrate in an amount from about 150 – 600% of the dry weight of the wiper. It should be noted that the amount of the sanitizing formula present in the wipe is a result effective variable. For example, as the amount of the sanitizing formulation increases, the application surface becomes more saturated and the formulation is able to clean more efficiently and effectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the sanitizing formulation present in the substrate in an amount from about 150 – 600% of the dry weight of the wiper as required by claim 1 since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454 USPQ 233 (CCPA 1955). In the present invention, one would have been motivated to optimize the level of sanitizing formulation based on the dry weight of the wiper in order to effectively and efficiently clean the desired surface.

As to claims 1, 27 and 35, Harrison teaches the claimed invention except fails to disclose that the quaternary ammonium compound is released from the substrate as a solution during use of the wiper in food service applications. Since the wipe of Harrison meets the structural and

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chemical limitations set forth by the Applicant and there is nothing on record that shows that the fabric of Harrison cannot be incorporated into a wipe for use in food service applications, it would have been obvious to incorporate the wipe of Harrison into use for a food service application motivated by the desire to expand the range of uses for the wipe.

4. Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodd et al. (US 6,656,456).

Dodd is directed to a skin deodorizing composition (Title).

As to claim 1, Dodd teaches a composition comprising antimicrobial quaternary ammonium compounds such as benzalkonium chloride (column 8, lines 5 – 20). Dodd teaches that the quaternary compound is present in the range from about 0.001% to about 0.8% by weight of the composition (column 9, lines 1 – 15). Dodd teaches that the composition can be incorporated into an insoluble substrate such as in the form of a treated wipe (column 24, lines 60 – 68).

As to claim 10, Dodd teaches a preservative may be present in the amount of about 0.0002% to about 0.2% by weight of the composition (column 20, lines 39 – 42).

As to claim 1, although Dodd does not explicitly teach the claimed log reduction for E. Coli of at least about 2 as required by claim 1, it is reasonable to presume that the properties are inherent to Dodd. Support for said presumption is found in the use of like materials (i.e. a substrate comprising a composition containing water and a quaternary ammonium compound in an amount of 0.001% to about 0.8% wt) which would result in the claimed properties. The

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burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties above would obviously have been present once the Harrison product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

As to claim 1, Dodd discloses the claimed invention except for that the quarternary ammonium compound is present in an amount less than 2000 parts per million of said solution as stated in claim 1 is a result effective variable. For example, the amount of the quarternary ammonium compound present directly impacts the biocidal effectiveness (Harrison, column 9, lines 1 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the amount of the quarternary ammonium compound present in an amount less than 2000 parts per million of said solution as stated in claim 1 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to create the wipe with the optimum amount of quarternary ammonium compound in order to have maximal biocidal effectiveness.

As to claim 1, Dodd discloses the claimed invention except for that the sanitizing formulation is present in the substrate in an amount from about 150 – 600% of the dry weight of the wiper. It should be noted that the amount of the sanitizing formula present in the wipe is a result effective variable. For example, as the amount of the sanitizing formulation increases, the application surface becomes more saturated and the formulation is able to clean more efficiently and effectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the sanitizing formulation present in the substrate in an amount from about 150 – 600% of the dry weight of the wiper since it has been held that where general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454 USPQ 233 (CCPA 1955). In the present invention, one would have been motivated to optimize the level of sanitizing formulation based on the dry weight of the wiper in order to effectively and efficiently clean the desired surface.

As to claim 1, Dodd teaches the claimed invention except fails to disclose that the quarternary ammonium compound is released from the substrate as a solution during use of the wiper in food service applications. Since the wipe of Dodd meets the structural and chemical limitations set forth by the Applicant and there is nothing on record that shows that the fabric of Dodd cannot be incorporated into a wipe for use in food service applications, it would have been obvious to incorporate the wipe of Dodd into use for a food service application motivated by the desire to expand the range of uses for the wipe.

Response to Arguments

5. Applicant's arguments filed April 26, 2004 have been fully considered but they are not persuasive.

In response to Applicant's Arguments that the concentration of quarternary ammonium compound would not be a result of routine experimentation, the Examiner requests that if the Applicant's claimed concentration of quarternary ammonium compound is an unexpected result, the Applicant should submit a 1.132 Declaration. The Applicant's assertion does not suffice as evidence.

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Conclusion

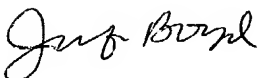
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Boyd

June 28, 2004



Ula C. Ruddock
Primary Examiner
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